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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,090	02/03/2004	Margaret H. Baron	HUIP-P02-060	4153

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EXAMINER	
SPECTOR, LORRAINE	
ART UNIT	**PAPER NUMBER**
1647	

DATE MAILED: 10/04/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/772,090	BARON ET AL.	
	Examiner	Art Unit	
	Lorraine Spector, Ph.D.	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-56 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-56 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Prior to setting forth the restriction requirement, it is noted that many of the claims as drafted read on multiple, patentably distinct inventions. Accordingly, those claims are grouped as being associated with all relevant inventions. After election, applicants will be required to amend the claims to read upon the elected invention only.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-18, 20-26, 31-34 and 36 as they are drawn to post-natal or *in vitro* stimulation of hematopoiesis, classified in class 424 or 514, subclass dependent upon species.

II. Claims 1-14, 18-22, 26 and 38-40, as they are drawn to post-natal or *in vitro* stimulation of vascular growth, classified in class 424 or 514, subclass dependent upon species.

III. Claims 27-30 as they are drawn to treatment of "developmental errors" of vascular growth, classified in class 424 or 514, subclass dependent upon species.

IV. Claims 27-30 as they are drawn to treatment of "developmental errors" of hematopoiesis, classified in class 424 or 514, subclass dependent upon species.

V. Claims 31, 35 and 37, as they are drawn to treatment of a subject for excess erythroid cells, classified in class 424 or 514, subclass dependent upon species.

VI. Claim 43, drawn to treatment of a subject for abnormally enhanced vascular growth, classified in class 424 or 514, subclass dependent upon species.

VII. Claims 44-56 as they drawn to a method of screening compounds for modulation of hematopoiesis using a transgenic mouse, classified in class 800, subclass 3.

VIII. Claims 44-56 as they drawn to a method of screening compounds for modulation of vascular growth using a transgenic mouse, classified in class 800, subclass 3.

The inventions are distinct, each from the other because of the following reasons:

Although there are no provisions under the section for "Relationship of Inventions" in M.P.E.P. § 806.05 for inventive groups that are directed to different methods, restriction is deemed to be proper because these methods appear to constitute patentably distinct inventions for the following reasons: Inventions I and II are related as different methods of using overlapping sets of products. The same is true of Inventions III and IV. While it is true that there are some products that may be used for both methods, there are also products that would only be useful in one method and not the other. Accordingly, each method does not *require* an active agent *required* by the other method. Additionally, the two methods require non-overlapping searches for hematopoiesis vs. vascular growth, which involve different processes and cell types. Claims V and VI, and claims VII and VIII are similarly distinct. Accordingly restriction is proper.

While the methods of Inventions I and II are drawn to *in vitro* or post-natal treatment, Inventions III and IV are specifically drawn to treatment of a prenatal embryo. The two sets of inventions require separate search and consideration because growth factors and cytokines often have different biological activity at the embryonic stage of life than post-natally. Further, the search for the conditions to be treated and what is known in the art about said conditions and their diagnosis and treatment will be non-overlapping. Thus, there must be separate search and consideration depending upon the developmental stage, which search would be burdensome. Accordingly restriction is proper.

The methods of Inventions V and VI are antithetical to those of Inventions I-IV, wherein growth of cells is being inhibited rather than stimulated. As such, the active agents of Inventions I-IV and those of Inventions V and VI are mutually exclusive, and require non-overlapping searches, which searches would be burdensome to the Examiner. .Accordingly restriction is proper.

The methods of claims VII and VIII are separate and distinct, each from each of the methods of Inventions I-VI. A method of screening for an active agent has separate and distinct method steps from a method of treatment; as methods must be considered primarily for their method steps, the searches are non-overlapping, and restriction is proper. Further, Inventions VII and VIII require transgenic animals, which are not required for any of the other groups, and

which constitute a separate area of search and consideration as evidenced by the separate classification. Accordingly, restriction is proper.

Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art due to their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Election of Species

Should applicants elect either Invention I or Invention II, applicants must further comply with two election of species requirements, as set forth below:

(A) This application contains claims directed to the following patentably distinct species: (a) Indian, (b) Desert, and (c) Sonic hedgehog. The species are independent or distinct because each is a distinct growth factor with a separate and distinct chemical structure and biological function, and each requires a separate search of the art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-6, 9-18, 20-26, 31-34 and 36 are generic to Invention I, and claims 1-6, 8-14, 18-22, 26 and 38-40 are generic to Invention II.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

(B) This application contains claims directed to the following patentably distinct species: (i) BMP-2 (ii) BMP-4 (iii) BMP-6 (iv) BMP-7. The species are independent or distinct because

because each is a distinct growth factor with a separate and distinct chemical structure and biological function, and each requires a separate search of the art.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-10, 12-18, 20-26, 31-34 and 36 generic to Invention I, and claims 1-10, 12-14, 18-22, 26 and 38-40 are generic to Invention II.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Lorraine M. Spector. Dr. Spector can normally be reached Monday through Friday, 9:00 A.M. to 3:00 P.M. at telephone number 571-272-0893.

If attempts to reach the Examiner by telephone are unsuccessful, please contact the Examiner's supervisor, Ms. Brenda Brumback, at telephone number 571-272-0961.

Certain papers related to this application may be submitted to Technology Center 1600 by facsimile transmission The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 C.F.R. § 1.6(d)). NOTE: If Applicant does submit a paper by fax, the original signed

copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Official papers filed by fax should be directed to **571-273-8300**. Faxed draft or informal communications with the examiner should be directed to ***571-273-0893.***

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Lorraine Spector, Ph.D.
Primary Examiner